

## COVER PAGE

# Clinical Evaluation of Subcutaneous Testosterone Implants in Men With Symptomatic Hypogonadism

NCT ID: not yet assigned

Protocol ID 7.890.514

Document Date: 10-08-2025

## Sample Size Calculation and Statistical Analysis Plan

Continuous variables will be described as means and standard deviations or as medians and interquartile ranges, according to their distribution. Categorical variables will be presented as absolute frequencies and percentages.

Repeated-measures analysis of variance (ANOVA) will be used to evaluate changes over time.

Multiple linear and logistic regression models will be employed to identify significant associations, adjusting for potential confounding factors. Corrections for multiple comparisons will be performed using the Bonferroni method.

Odds ratios (ORs) will be used as measures of the magnitude of association between categorical variables, and 95% confidence intervals will be reported as measures of precision. A  $p$  value  $< 0.05$  will be considered statistically significant. Statistical analyses will be performed using GraphPad Prism software (version 10.0.0; GraphPad Software, Boston, MA, USA).